

## REMARKS

### I. INTRODUCTION

In response to the Office Action dated September 9, 2004, claims 9, 10, 22 and 68 have been canceled, and claims 1, 21 and 34 have been amended. Claims 1-8, 16-21, 23, 33, 34, 46-67 and 69 remain in the application. Entry of these amendments, and reconsideration of the application, as amended, is requested.

### II. CLAIM AMENDMENTS

Applicants' attorney has made amendments to the claims as indicated above. These amendments were made solely for the purpose of clarifying the language of the claims, and do not introduce new matter or require further search. Claim 1 has been amended, as suggested by the Examiner, to delete "vaccine". Claim 1 has been amended to incorporate the limitations of canceled claim 22. Claims 21 and 34 have been rewritten in independent form, incorporating the limitations of claim 1, from which each previously depended. Accordingly, these amendments do not raise new issues for examination and their entry is respectfully requested.

### III. PRIOR ART REJECTIONS

In paragraph (3) of the Office Action, claims 1-6, 16, 17, 33, 58, 59, 60, 61 and 63 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Mizzen. In paragraph (4) of the Office Action, claims 1-8, 16, 17, 33 and 58-63 were rejected under 35 U.S.C. §103(a) as allegedly obvious in view of the combination of Mizzen and Wang. In paragraph (5) of the Office Action, claims 1-6, 16, 17, 23, 33, 58, 59, 60, 61, 63 and 69 were rejected under 35 U.S.C. §103(a) as allegedly obvious in view of the combination of Mizzen and either Dong or Heath. In paragraph (6) of the Office Action, claims 1-6, 16-18, 33, 58, 59, 60, 61, 63 and 64 were rejected under 35 U.S.C. §103(a) as allegedly obvious in view of the combination of Mizzen and Cheever. In paragraph (7) of the Office Action, claims 1-6, 16-18, 20, 21, 33, 58, 59, 60, 61, 63 and 64 were rejected under 35 U.S.C. §103(a) as allegedly obvious in view of the combination of Mizzen and Cheever in view of Eberlein. In paragraph (8) of the Office Action, claims 1-6, 16, 17, 19, 33, 58, 59, 60, 61 and 63 were rejected under 35 U.S.C. §103(a) as allegedly obvious in view of the combination of Mizzen and Hudziak.

Applicants have amended claim 1 to incorporate the limitations of claim 22 ("wherein the complex has been heated so as to enhance binding of the hsp110 polypeptide to the immunogenic polypeptide"), which in turn incorporates these limitations into the remaining claims that were rejected in view of the prior art. Because each of claims 1-8, 16-20, 23, 33, 58-64 and 69 now recites the limitations of claim 22, these claims are allowable over the cited references, and withdrawal of the prior art rejections is respectfully requested.

Although claim 21 has not been amended to incorporate these limitations, Applicants respectfully note that the inclusion of claim 21 with the other claim rejections appears to be in error. The Examiner has pointed to no teachings in any of the cited references that disclose or suggest the features of claim 21 ("wherein the cancer antigen is a colon cancer antigen"). Accordingly, Applicants have rewritten claim 21 in independent form. Because the Patent Office has failed to make a *prima facie* case of obviousness in connection with claim 21, it is requested that the rejection of claim 21 be withdrawn.

#### IV. NON-ART REJECTIONS

In paragraph (11) of the Office Action, claims 1-5, 7-10, 16-23, 34 and 46-57 were rejected under 35 U.S.C. §112 as allegedly lacking an enabling disclosure in the specification. The Examiner acknowledged that the specification is enabling for a method for eliciting an anti-tumor immune response against a pre-existing tumor in a subject, but questioned the enablement for a method of prophylactically generating an anti-tumor response, particularly in the context of a cancer patient which is not an experimental animal in which the tumor occurs as a result of transplantation of tumor cells. The Examiner further indicated that amendment of the claims to delete the word "vaccine" would overcome the above rejection. In response, Applicants have amended the claims in accordance with the Examiner's suggestion, and therefore respectfully request withdrawal of the rejections under 35 U.S.C. §112.

Although Applicants have deleted "vaccine" from the claims to facilitate prosecution in view of the Examiner's indication that this amendment would overcome the rejection, Applicants note the following for the record. A vaccine can be used both prophylactically and therapeutically, and so long as the vaccine composition is enabled to the extent that one skilled in the art is taught how to make and use the vaccine composition, the composition is enabled. With regard to enablement for

the method of inhibiting the development of cancer in a subject, this can also be useful in both prevention of disease and inhibiting disease progression. An animal model in which administration of the vaccine composition prior to development of tumor inhibits disease progression is clearly an art-accepted model for both therapeutic and prophylactic treatment of cancer.

The Examiner's statements in paragraph (12) of the Office Action indicate that the Examiner would accept nothing short of a clinical trial in which the vaccine composition were administered to healthy patients who were followed over an extended period of time and found cancer-free in order to adequately enable the claimed method. The Examiner appears to be construing the claims to encompass a method for guaranteeing a cancer-free existence. Applicants respectfully note, however, that claim 34 recites a "method for inhibiting the development of a cancer in a subject". This means slowing disease progression, not guaranteeing a lifetime of cancer-free health. Applicants respectfully note that "inhibit" means "to decrease, limit, or block the action or function of (an enzyme or organ, for example)"; and "development" means "progression". Applicants clearly have provided convincing support to enable one skilled in the art to use the claimed composition to limit progression of cancer.

Applicants have presented data from an art-accepted model of cancer development that clearly support prophylactic use of the claimed vaccine composition. These data should be accepted as sufficient support for enablement, as required by the Federal Circuit's decision, *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995). Even without amending the claims to delete "vaccine", Applicants maintain that the specification clearly provides an adequate disclosure enabling those skilled in the art to make and use the claimed invention.

#### **V. WITHDRAWN REJECTIONS & ALLOWABLE SUBJECT MATTER**

In paragraph (10) of the Office Action, the rejection of claims 1-6, 16, 17, 22, 33, 58, 59, 60, 61, 63 and 68 under 35 U.S.C. §103(a) as being unpatentable over Mizzen in view of Wallen was withdrawn. In paragraph (13) of the Office Action, claim 68 was objected to as being dependent upon a rejected base claim, but indicated as allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In paragraph (14) of the Office Action, the Examiner indicated that all other rejections and objections set forth in the prior Office Action were withdrawn.

Applicants appreciate the Examiner's indication of allowable subject matter, and have amended the claims accordingly. For example, all the limitations of previous claim 68 appear in claim 33 in view of the amendment to claim 1.

## VI. RESPONSE TO ADVISORY ACTION

Applicants acknowledge and appreciate the Advisory Action dated December 3, 2004, which was issued in response to the Amendment submitted by Applicants on November 8, 2004. The Amendment submitted on November 8, 2004, contained the same amendments and arguments presented herein, with the exception of claims 9 and 10. The Advisory Action indicated that claims 9 and 10, as amended by the November 8, 2004 Amendment to delete "vaccine", raised new issues requiring further consideration by the Examiner. For this reason, the Amendment dated November 8, 2004 could not be entered.

To facilitate prosecution and place the application in immediate condition for allowance, Applicants have canceled claims 9 and 10, reserving the right to pursue the subject matter of these claims in a future application. The Advisory Action indicated no other basis for refusal to enter the November 8, 2004 Amendment, nor did the Advisory Action comment on the status of the remaining claims. Applicants' undersigned representative has made three attempts to contact the Examiner by telephone since receiving the Advisory Action on December 6, 2004, to confirm that no other issues remain to be resolved in this application, provided the present Amendment is entered. Because the Examiner was not able to return these telephone calls prior to the due date for this response, Applicants request that, should any further issues remain, the Examiner contact Applicants' undersigned representative by telephone so that such issues may be resolved promptly.

**VII. CONCLUSION**

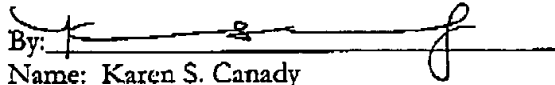
In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

GATES & COOPER LLP  
Attorneys for Applicant(s)

Howard Hughes Center  
6701 Center Drive West, Suite 1050  
Los Angeles, California 90045  
(310) 641-8797

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By:   
Name: Karen S. Canady  
Reg. No.: 39,927

KSC/amb